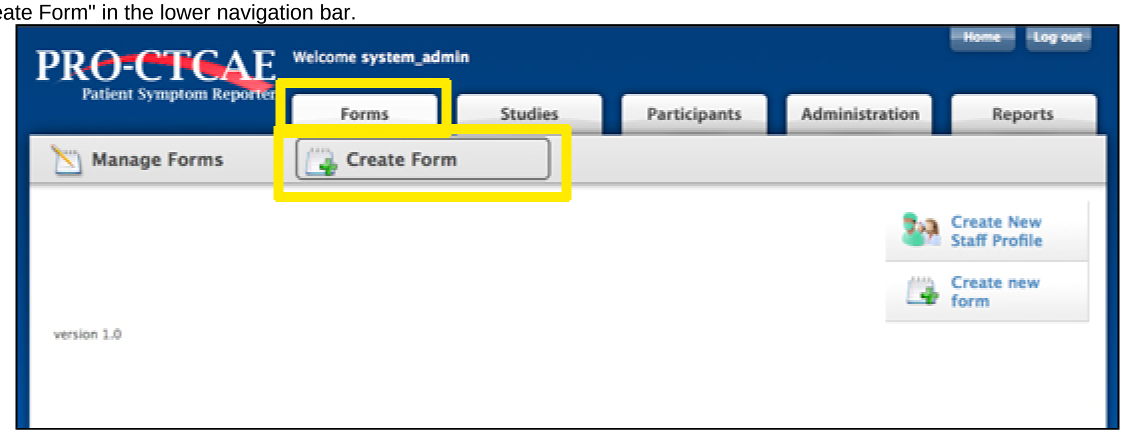
Create Form

Forms   Edit Form

Important

The Lead Site CRA and Lead Site PI may create forms in PRO-CTCAE.
Hover over the "Forms" tab in the top navigation bar.

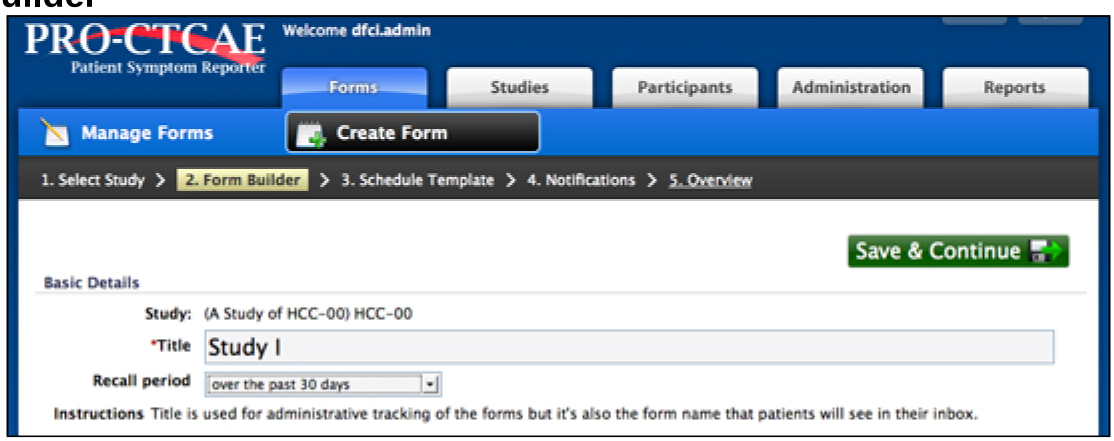
Click on "Create Form" in the lower navigation bar.



Select Study

To enter the study, start typing either part of the study identifier or title. A drop-down menu of studies will appear. Scroll down and click on the corresponding study. If you choose the wrong study and want to clear the field, click on the white "X" in the small black icon.

Form Builder



Basic Details

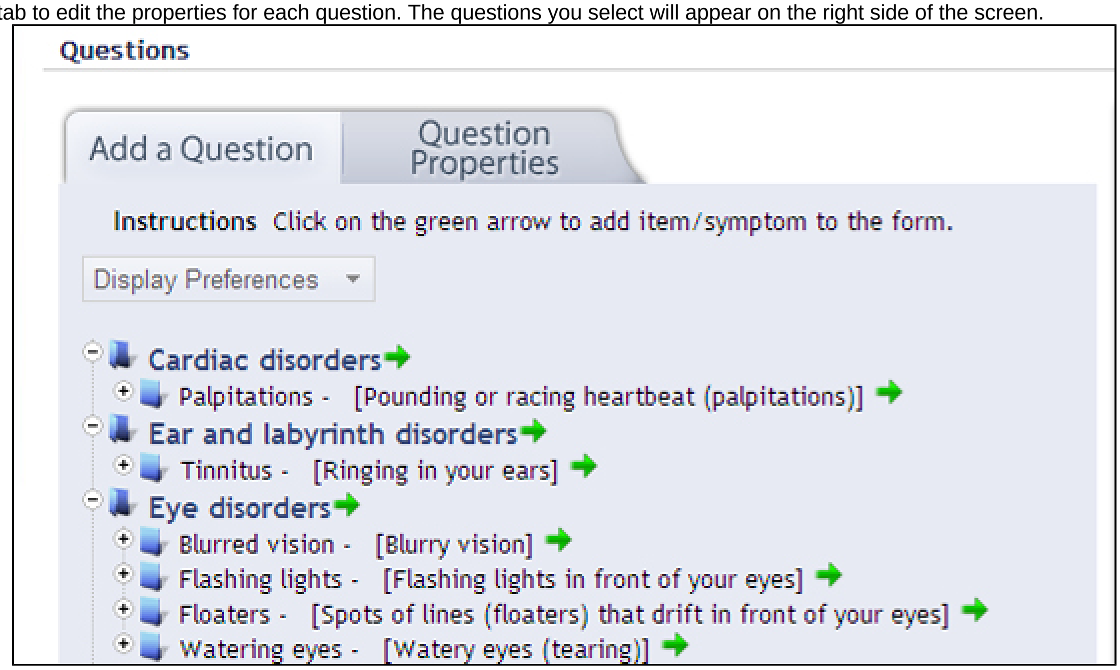
Study: The name of the study is described here. This is a read-only field.

Title: Add the title for your form here. This is required. Try to be as descriptive but concise as possible, in order that research staff can easily identify the form for this study.

Recall Period: Select the recall period for your form using the drop-down menu. This is the period of time over which the patient will consider their symptoms. The default option is "Over the past 7 days," for example, "Please think back over the past 7 days, what was the severity of your constipation at its worst?" Other options include "Over the past 30 days," "Since your last cancer treatment," and "Other." Select "Other" if you want to create a different recall period, and a text field will appear where you can enter what you want.

Questions

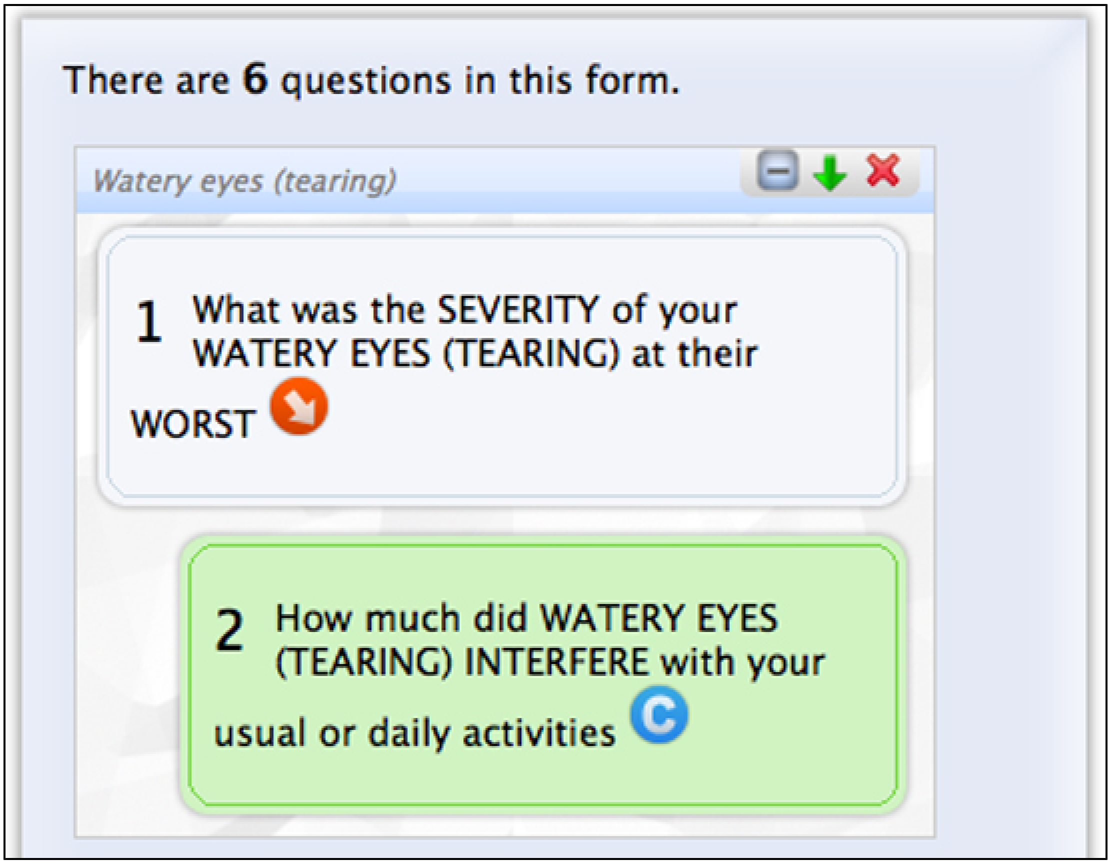
On the left side of the screen, you will see a list of all possible PRO-CTCAE symptoms that can be added to this form under the first tab, as well as a second tab to edit the properties for each question. The questions you select will appear on the right side of the screen.



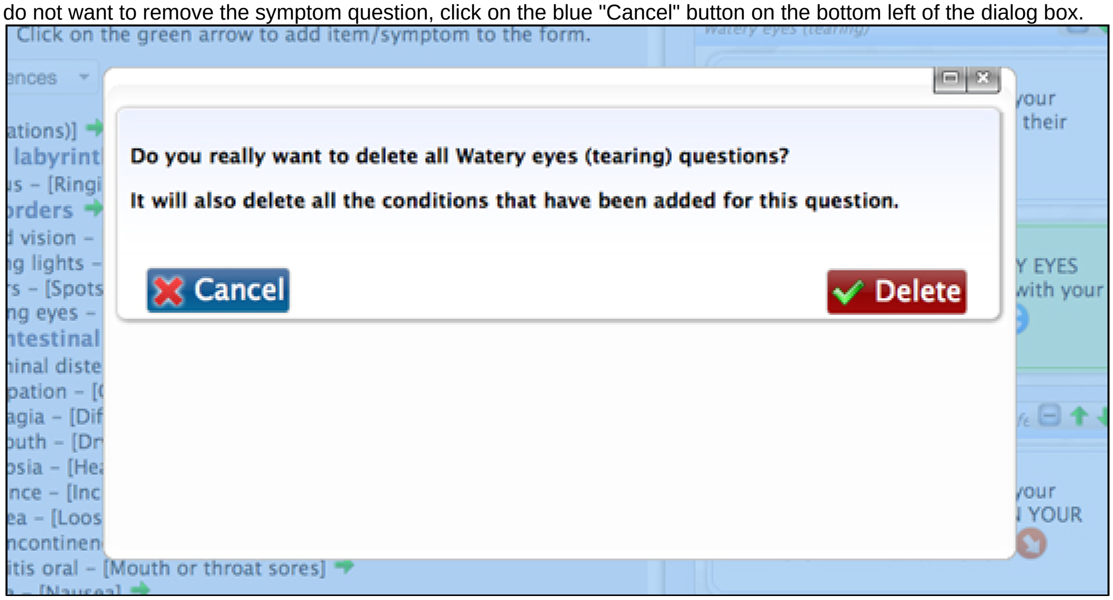
Add a Question

Display Preferences: Use the drop-down menu to select how you want the symptom terms organized while building your form: "Participant Term Only," "CTCAE v4 / MedDRA Term Only," "Both (Participant Term First)," or "Both (CTCAE v4 / MedDRA Term First)." The default option is "Both (CTCAE v4 / MedDRA Term First)."

1. To add question(s) about a single symptom, click on the green arrow next to the symptom term. Your question(s) will be added to your form, as shown on the right side of the screen.
2. To add all the questions from an entire group of symptoms or SOC, system organ class, click on the green arrow next to the blue bold group line. All questions for that group will appear on the right side of the screen, as it would appear on your form.
3. To see what questions are associated with a particular symptom, click on the symptom name or click on the "+" sign in the small white circle before the symptom term. To hide the questions, click again on the symptom name or click on the "-" sign in the small white circle. A question that contains a "C" in a blue circle is conditional. If a participant does not have the symptom, or if the symptom is not severe, the conditional question will not appear.
4. To hide the individual symptoms in a particular group, click on the group name or click on the "~~" sign in the small white circle before the group name. To see the individual symptoms in a particular group, click again on the group name or on the "~~" sign in the small white circle before the group name.
5. Once you have populated your form, you have several options. To see the individual symptoms in a particular group, click on the "+" sign in the small white box. To close the box, click on the "-" sign.



6. To change the order of symptom questions listed in your form, click on the up or down green arrows in that symptom's box to move the questions earlier or later.
7. To remove all of a symptom's questions from your form, click on the red "X" in that symptom's box on the right side of the screen. A dialog box will appear and ask you to confirm Click on the red "Delete" button on the bottom right of the dialog box. If you change your mind and do not want to remove the symptom question, click on the blue "Cancel" button on the bottom left of the dialog box.



Question Properties

This is where you can indicate whether a participant's response to a question on your form is mandatory. The default that is currently set makes all questions mandatory.

After you've added all the questions to the form:

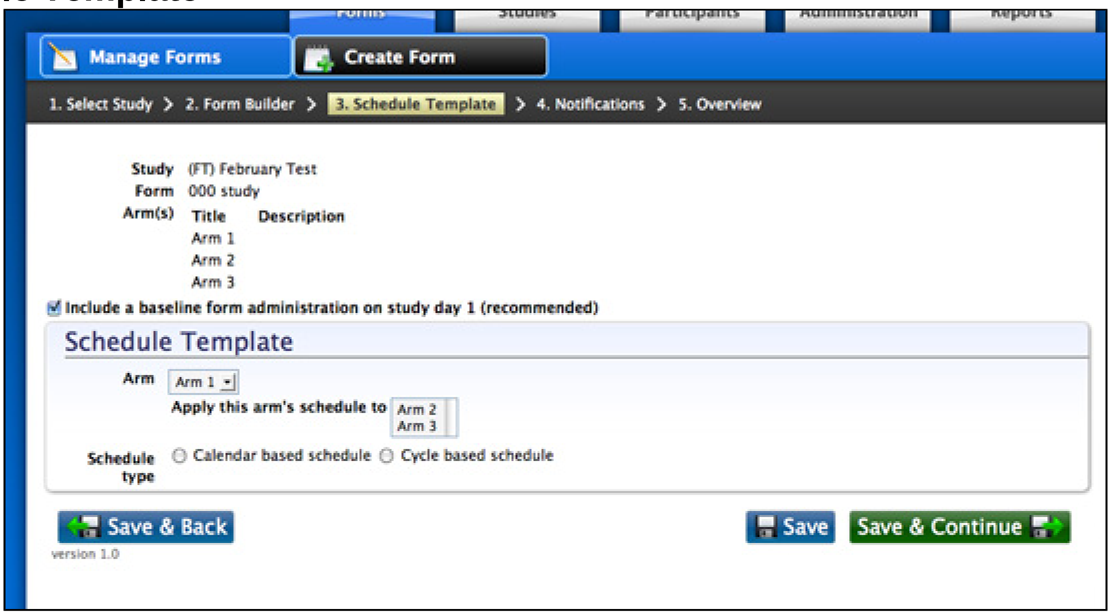
1. Click on the "Question Properties" tab.
2. On the right side of the screen, you'll see the first question in your form highlighted in blue.
3. On the left side of the screen, select the "No" radio button if you don't want to make answering this question mandatory.

4. Repeat this step for other symptom questions that you would like to change from being mandatory. Also, this may be useful if you would like to make conditional questions not required after a positive response to the symptom.

You now have three options:

1. Click on the blue "Save & Back" button on the bottom left of the screen to save your work and go to the "Select Study" screen to being creating a new form for another study.
2. Click on the blue "Save" button on the bottom right of the screen to save your work.
3. Click on the green "Save & Continue" button on the bottom right (or the top right of the screen) to save your work and go to the "Schedule Template" section.

Schedule Template



Choose the first study arm by using the drop-down menu. You may then apply this arm's schedule to another arm by clicking on the appropriate arm in the box. After you select the appropriate arm, click "Save." You may repeat this process as many times as necessary. Remember to click "Save" after applying the schedule to each new arm.

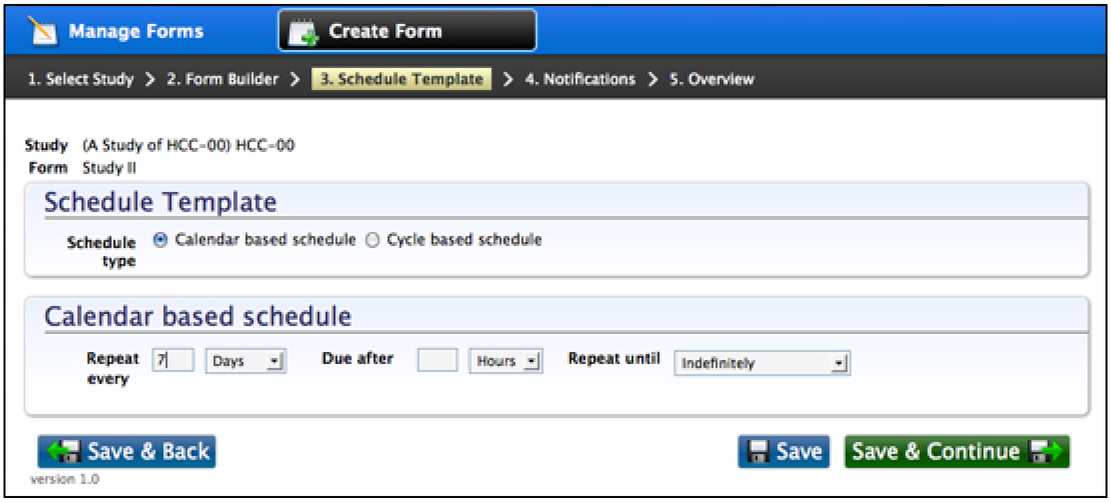
If all arms will have the form scheduled on the same days, check the box to apply the schedule to all of the study arms.

If you would like to administer a baseline form on day 1 of the study, check the blue box. It is recommended that you do so.

Schedule Type

Click on the radio button to set up a schedule based on the calendar or cycles:

Calendar-Based Schedule

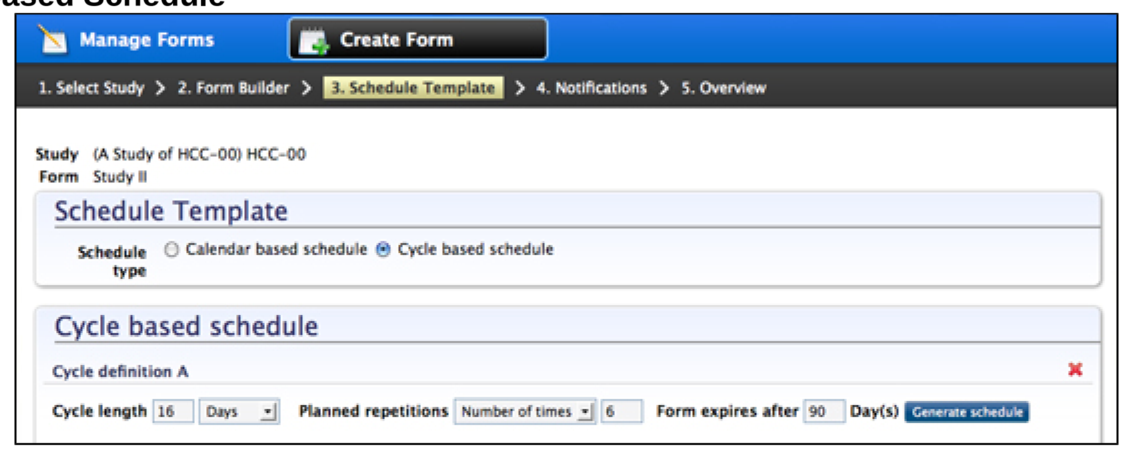


Repeat Every: Enter the number of days, weeks, or months between administration of forms for participants to report their symptoms. Use the drop-down menu to select "Days," "Weeks," or "Months." "Days" is the default.

Due After: Enter the number of hours, days, or weeks you want to set as the deadline for each form (after it is scheduled). Use the drop-down menu to select "Hours," "Days," "Weeks." "Hours" is the default.

Repeat Until: Use the drop-down menu to choose whether to repeat this form indefinitely, until a certain date, or until patients have submitted a certain number of completed forms. If you select "Date," you'll see a new field where you can enter the end date. Type the date in the mm/dd/yyyy format, or click on the calendar icon to choose the date. If you select "Number of repetitions," you'll see a new field where you can enter the number of forms you want to collect from each participant.

Cycle-Based Schedule



Click on the blue "Add" button to create your cycle definition.

Cycle Length: Enter the number of days, weeks, or months you want to establish as the length of the cycle. Use the drop-down menu to select "Days," "Weeks," or "Months." "Days" is the default.

Planned or Indefinite Repetitions: Enter the number of times you want this form to repeat, or choose "Indefinite" in the drop-down menu. "Number of times" is the default. If you select "Indefinite":

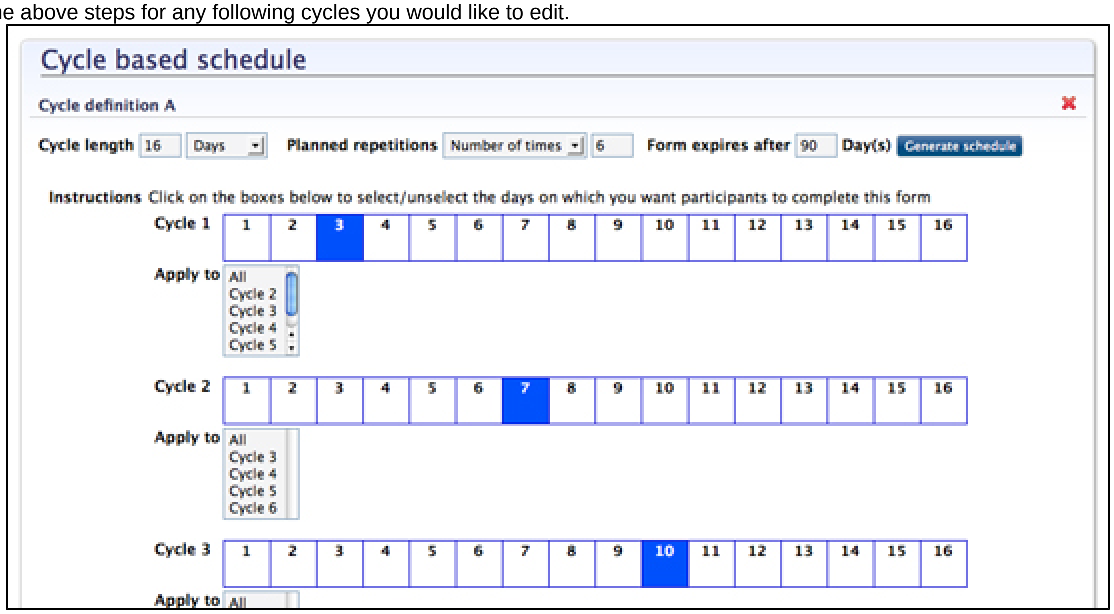
1. A calendar row that contains a box for each day in the cycle will appear for the number of repetitions you chose. If you selected "Indefinite," only the calendar days for the 1 cycle will appear.
2. Click on the boxes to select the days on which you want participants to complete the form.
3. If you change your mind and want to unselect a day, click on the box again.

Form Expires After __ Day(s): Enter the number of days you want this form to be available after the scheduled date.

If you selected "Number of times" for the "Planned Repetitions" option earlier, you will need to click on the blue "Generate" button on the right side of your screen to create your schedule:

1. The number of cycles you'll see will depend on the number you entered for "Planned Repetitions."
2. In the "Cycle 1" row, click on the boxes to select the days on which you want participants to complete the form.
3. In the "Apply To" field, you may apply the days you selected to schedule the form in this cycle to all remaining cycles or a single later cycle.

4. If you change your mind and want to unselect a day, click on the box again. If you want to update any later cycle to match your new settings for "Cycle 1," click on "All" in the "Apply To" field.
5. Repeat the above steps for any following cycles you would like to edit.



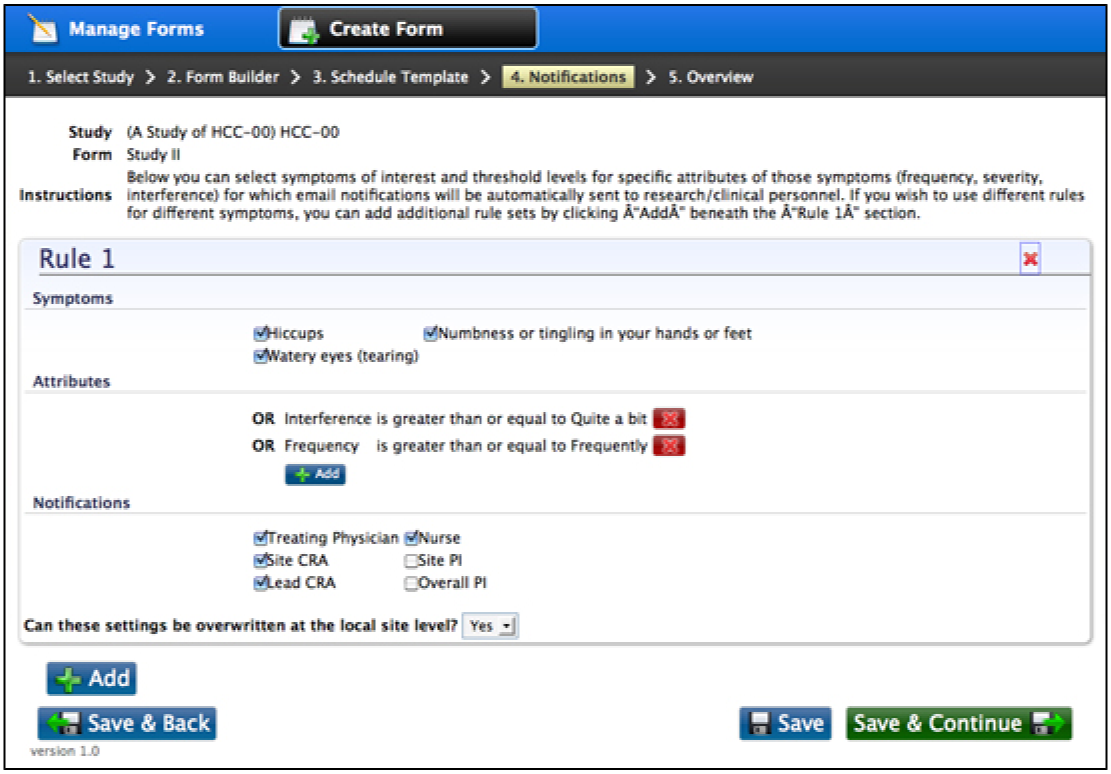
If you want to delete this cycle definition, click on the red "X" in this area. A dialog box will ask to confirm. If you are sure, click on the red "Delete" button on the bottom right of the dialog box. If you change your mind, click on the blue "Cancel" button on the bottom left of the dialog box.

If you want to add another cycle definition, click on the blue "Add" button again and repeat the above steps. Each cycle definition will be added consecutively after the prior cycle definitions. If you change your mind, click on the red "X."

You now have three options:

1. Click on the blue "Save & Back" button on the bottom left of the screen to save your work and go to the "Form Builder" screen if you want to edit or return to the form.
2. Click on the blue "Save" button on the bottom right of the screen to save your work and navigate elsewhere.
3. Click on the green "Save & Continue" button on the bottom right of the screen to save your work and go to the "Notifications" section.

Notifications



Rule 1

Set the criteria for sending email notifications based on a participant's response:

Symptoms: here you'll see all the symptoms listed on your form. Uncheck any symptoms you don't want to include in this group or that should not prompt any email notification (regardless of how the participant responds).

Attributes: for the symptoms that are included in this rule, you'll see what level of response is the default to trigger an email notification:

- If you want to delete an attribute (frequency, severity or interference) from this rule, click on the red "X" next to that line. You will not be asked to confirm this deletion.
- If you want add another attribute to this rule, click on the blue "Add" button in this area.

Notifications: the check boxes indicate which staff members will be notified when a participant's responses match the attribute responses you established. Click to check or uncheck a box to add or remove a staff person from this list. The treating physician, nurse, site CRA, and lead CRA are checked to be notified by default.

Can these settings be overwritten at the local site level?: Use the drop-down menu to select "Yes" or "No." "Yes" is the default setting.

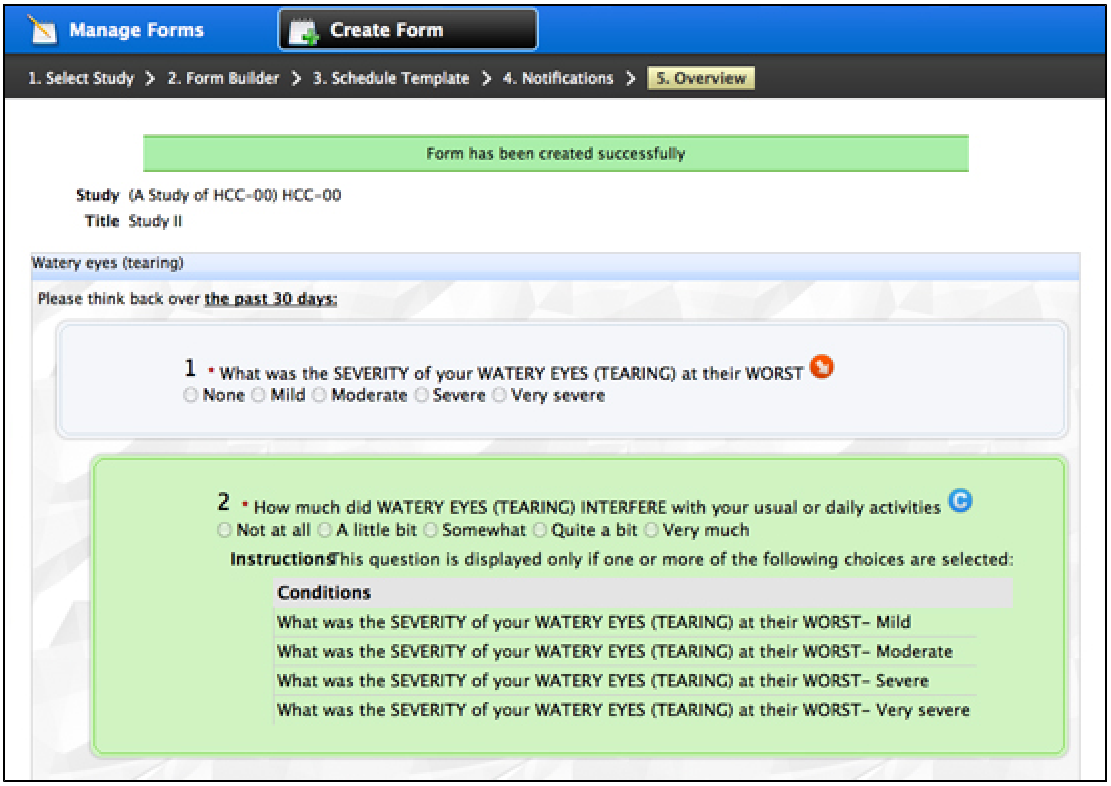
If you want to add a new rule, click on the blue "Add" button at the bottom of the screen and repeat the above steps. This can be useful if you want to create a different notification rule for a different set of symptoms. For instance, if the staff wanted to be notified for a severe patient report for pain, but limit to a very severe grade before being notified for fatigue.

To remove a rule entirely, click on the red "X" in the top right of the box for that particular rule. A dialog box will ask if you're sure you want to delete this rule. If you are, click "OK." If you change your mind, click "Cancel."

You now have three options:

1. Click on the blue "Save & Back" button on the bottom left of the screen to save your work and go back to the "Schedule Template" screen.
2. Click on the blue "Save" button on the bottom right of the screen to save your work and navigate elsewhere.
3. Click on the green "Save & Continue" button on the bottom right of the screen to save your work and go to the "Overview" section.

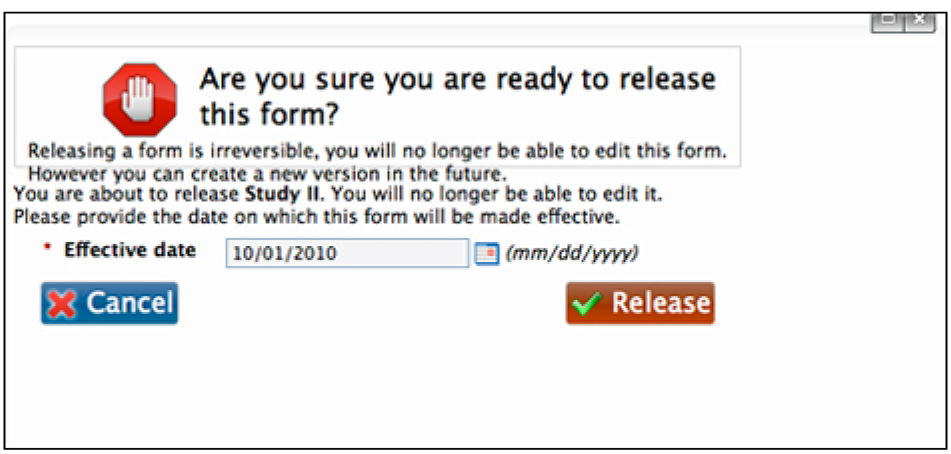
Overview



Here you will find the confirmation screen showing the survey you created to the requirements you've entered on the previous three screens. Questions that require a participant's response (that were checked as mandatory) are marked with an asterisk. This is a read-only page.

You now have two options:

1. Click on the blue "Finalize Form" button on the bottom left of the screen to release this form. A dialog box will ask you to confirm this Form to be active. **Once you release a form, you can no longer edit it.**
!18createform.jpg|align=center,border=1!In the confirmation box, you can change the form's effective date from the default of today's date. Type the date in the mm/dd/yyyy format, or click on the calendar icon to choose the date. Once you are ready to release the form, click on the red "Release" button. If you change your mind, click on the blue "Cancel" button. Once you release a form, you will be taken to the "Manage Forms" screen.



2. Click on the green "Finish" button on the bottom right of the screen to save this form and go to the PRO-CTCAE homepage. **This option will save your form but does not finalize the form to be released to study participants. You can return to it and make changes.**